PROCEF (CEFIXIME U.S.P) Tablets-Suspension Antibiotic

COMPOSITION:

Procef Tablet: Each film coated tablet contains: Cefixime U.S.P...400 mg.

Procef Suspension: Each 5 ml contains;100 mg Cefixime U.S.P (on reconstitution).

ACTION:

Procef is an orally active Cephalosporin antibiotic which has bactericidal activity against wide variety of gram +ve and gram-ve organisms.

INDICATIONS:

Procef is indicated in following infections:

Upper Respiratory Tract Infections:

Sinusitis,pharyngitis, laryngitis, tonsillitis & otitis media. Lower Respiratory Tract Infections:

Acute bronchitis, acute exacerbations of chronic bronchitis and Pneumonia.

Gastrointestinal tract infections:

Enteric fever specially for Multi Drug Resistant (MDR) typhoid. Urinary Tract Infections:

Cystitis, cystourethritis, cervicitis, uncomplicated pyelonephritis and uncomplicated gonorrhea.

DOSAGE AND ADMINISTRATION:

Absorption of Procef is not significantly modified by the presence of food. The usual course of treatment is 5-14 days. Adults & Children Over 12 years:

The usual recommended adult dosage is 400 mg daily to be administered as a single dose or in two divided doses. Children Below 12 vears:

The recommended dosage for children is 8 mg/kg/day administered as single dose. Following is suggested as a general guide for prescribing in children.

Age	Procef / Day Tablet	Procef / Day Suspension
1 - 4 years	100 mg	1 teaspoonful
5 - 9 years	200 mg	2 teaspoonful
9 - 12 years	300 mg	3 teaspoonful

The dosage in children aged six months to one year should be calculated on 8 mg /kg/day according to body weight. **Dosage in Renal Impairment: Procef** doses should be reduced in patients with impaired renal function. Normal dose may be given in patients with creatinine clearance of 20ml/min or greater. **CONTRA-INDICATIONS:** Patients with known hypersensitivity to cephalosporin antibiotics.

WARNING:

Cephalosporin should be given with caution to penicillin sensitive patients.

INTERACTION:

No significant drug interactions have been reported to date. **OVER DOSAGE:**

There is no experience with overdoses of Cefixime. Adverse reactions seen at dose levels upto 2 gm Cefixime in normal subject.

SIDE EFFECTS:

Procef is generally well tolerated. The most frequently reported side effects of **Procef** are gastrointestinal disturbances, specially diarrhea. Other side effects seen less frequently are nausea, abdominal pain, dyspepsia, vomiting, flatulence, headache & dizziness.

HYPERSENSITIVITY REACTION:

Allergies in the form of rash , pruritus, urticaria have been reported. These reactions usually subsides on discontinuation of therapy.

DIRECTIONS FOR PREPARATION OF SUSPENSION:

Shake bottle well to loosen the powder. Add boiled and cooled water in the bottle up to the red mark given on label to make suspension and shake vigorously. Add more water up to the red mark if required. Close the cap and shake well till the oral suspension prepared for the use.

The reconstituted suspension can be used up to 7 days when stored at room temperature and up to 14 days when refrigerated. **INSTRUCTIONS:**

Shake well before use.

Store below 30°C. Do not freeze.

Protect from sunlight. For oral use only.

Keep out of the reach of children.

Reep out of the reach of children.

To be dispensed on prescription of Registered Medical Practioner only.

PRESENTATION:

Procef Tablet 400mg: Pack of 5 tablets in blister. **Procef Suspension:** Dry powder for oral suspension (reconstituted volume 30ml).

مسلوب گولیاں استیشن مرم) یو۔ایس۔ پی گولیاں 400 ملی گرام/مسینشن 100 ملی گرام/5 ملی لیٹر 30 ڈگری سینٹی گریڈ سے کم پر کٹیں۔ دھوپ، گرمی اورنی سے محفوظ رکٹیں ۔ تمام اوویات بچوں کی بینچ سے دورر کٹیں ۔ ڈاکٹر کی ہدایات کے مطابق استعال کریں۔ صرف متنددًا کٹر کے نسخہ پر فراہم کریں۔

Manufactured by: PHARMEDIC LABORATORIES (PVT) LIMITED. 16 Km. Multan Road, Lahore - Pakistan